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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,624	08/15/2005	Christopher Anthony Morris	4501-1015	7843

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YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

NOTIFICATION DATE	DELIVERY MODE
10/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,624	MORRIS ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/24/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,10 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. All previous rejections are withdrawn in view of the amendments to the claims. As noted in the remarks, the cited references do not teach the newly added method limitations about determining milk content based on proportions of cows.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 9, and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejected claims are drawn to a method of determining the level of saturated fatty acids relative to the level of unsaturated fatty acids in bovine milk. The claimed invention falls within an enumerated statutory category, namely a process.

The claims include steps of "determining" which β-casein genotypes are present in two or more cows, analyzing the genotype test results and using the results of the analysis to determine the level of saturated fatty acids in milk obtainable from the cows.

In re Bilski No. 2007-1130 (Fed Cir. October 30, 2008) characterizes its machine-transformation test as "the governing test for determining patent eligibility of a process under section 101." Under this test, a process claim is patent-eligible if (and as applied in Bilski apparently only if): "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." The claims are not directed to patent-eligible subject matter since they are not tied to any particular machine or apparatus and they do not require any particular article to be transformed into another state or thing.

None of the rejected claims requires the transformation of an article or physical object to a different state. For example, one could determine the genotypes of the cows based on previously performed genotyping assays, and the remaining analysis is computational. Additionally, there is no result tied to the physical world. There is no transformation of an article or physical object to a different state. Transformation of data is not considered a physical transformation.

As clearly noted in In re Comiskey No. 2006-1286 (Fed. Cir. Sept. 20, 2007), "the Supreme Court has reviewed process patents reciting algorithms or abstract concepts in claims directed to industrial processes. In that context, the Supreme Court has held that a claim reciting an algorithm or abstract idea can state statutory subject matter only if, as employed in the process, it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter. 35 U.S.C. § 101." In In re Comiskey, the PTO noted, "[t]he Supreme Court has recognized only two instances in which such a method may qualify as a section 101 process: when the process 'either [1] was tied to a particular apparatus or [2] operated to change materials to a 'different state or thing.''" (quoting Flook, 2006-1286 17 437 U.S. at 588 n.9). In Diehr, the Supreme Court confirmed that a process claim reciting an algorithm could state statutory subject matter if it: (1) is tied to a machine or (2) creates or involves a composition of matter or manufacture. 450 U.S. at 184. There, in the context of a process claim for curing rubber that recited an algorithm, the Court concluded that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." Id. (quoting Benson, 409 U.S. at 70);13 see also In re Schrader, 22 F.3d 290, 295 (Fed. Cir. 1994)

(holding when a claim does not invoke a machine, "§ 101 requires some kind of transformation or reduction of subject matter").

Finally, the Comisky opinion states that mental processes- or processes of human thinking- standing alone are not patentable even if they have practical application. The Supreme Court has stated that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." Benson, 409 U.S. at 67 (emphasis added). In Flook the patentee argued that his claims did not seek to patent an abstract idea (an algorithm) because they were limited to a practical application of that idea-updating "alarm limits" for catalytic chemical conversion of hydrocarbons. 437 U.S. at 586, 589-90. The Court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that "[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula." Id. at 590.

There is no recitation in the claims of producing a real-word result that is tied to a machine or apparatus or causes a transformation of an article. In other words, the outcome of the rejected methods lack a tie to the machine or apparatus and lack a physical transformation. Thus the claims are rejected as encompassing non-statutory subject matter.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 9-10, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a rejection for new matter.

In claim 1, the amendments to step (b) and (c) are new matter. In particular, the newly added step of "analyzing the genotype test results from step (a) to determine the proportion of cows that have" DNA encoding certain β-casein variants does not appear to have basis in the specification. The specification teaches determining the genotype of a 1,114 bovines, but is silent as to determining the proportion of cows with particular genotypes. Claim 1 further requires using the proportions to determine the level of unsaturated fatty acids relative to the level of unsaturated fatty acids in milk obtainable from the cows, and the examiner was also unable to locate basis for methods which use proportions of genotypes to determine the levels of fatty acids in milk.

Claim 17 is newly added. Part (b) requires determining the proportion of cows that have DNA encoding β-casein having particular genotypes that are required to provide a predetermined level of saturated fatty acids relative to the level of unsaturated fatty acids. There is no basis in the specification for the determining the proportion of cows step, in particular, there is no discussion of using certain proportions of cows having different genotypes to achieve a particular "predetermined level" of saturated fatty acids in obtained milk.

The examiner was not able to identify basis in the specification for this step either, where proportions genotypes are used to determine relative levels of fatty acids in cows. Applicants point to particular portions of the specification to provide support for "the amendment to the claims," but none of these portions of the specification discuss proportions, nor do they disclose determining milk levels based on proportions.

Notes:

Applicant refers to the specification, page 6, lines 1-10. This portion teaches A1 milk has a higher percentage of saturated fatty acids and a lower percentage of unsaturated fatty acids compared to A2 milk, and thus, milk that is substantially free of β-casein A1 will produce milk fat that has lower levels of saturated fatty acids and medium chain fatty acids. There is no mention of calculating proportions of cows that have particular genotypes.

Applicant refers to the specification, page 8, lines 1-12. This portion teaches to use the test for β-casein genotype to select animals to breed herds for milking, preferably forming herds where A1 β-casein is absent from the herd, or where only A2 milk is present. There is no discussion here about determining the fatty acid content of milk based on proportions of particular genotypes present.

Applicant further points to the discussion of the examples. The examples teach genotyping and analysis of milk from 1114 bovine progeny (p. 9). All of the animals sampled were either A1 or A2 homozygous or heterozygous for A1/A2 (p. 10). The specification never actually discloses the levels of fatty acids in the particular types of milk, only the differences in levels in the contrasted genotypes. There is neither explicit nor implicit teaching of determining "the proportion" of cows that have particular genotypes.

No explicit or implicit teaching of using determined proportions to determine the level of unsaturated fatty acids in milk obtainable from the cows.

5. Claims 1-6, 9, 10, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejected claims are drawn to methods of determining the level of saturated fatty acids relative to the level of unsaturated fatty acids in milk by analyzing the proportion of cows that have DNA encoding particular β-casein genotypes and using the results of the analysis step of (b) to determine the level of saturated fatty acids relative to the level of unsaturated fatty acids in milk obtainable from the cows. Thus, the practice of the invention requires the knowledge of a reliable association between the proportion of particular genotypes of cows present in a population and the relative level of saturated fatty acids in the population. The rejected claims also include methods for obtaining bovine milk having a particular predetermined level of fatty acids based upon determining the β-casein genotypes, calculating proportions necessary to determine particular levels of fatty acids, and using the proportions to select cows with the appropriate genotypes.

There is no guidance in the specification as to what proportions of particular genotypes in herds would be required to obtain milk of any particular predetermined level of saturated fatty acids relative to unsaturated fatty acids. There are no working examples of the claimed methods.

The specification provides examples which teach genotyping and analysis of milk from 1114 bovine progeny (p. 9). All of the animals sampled were either A1 or A2 homozygous or

heterozygous for A1/A2 (p. 10). Compared to A1, milk from animals having A2 genotype had a significantly higher percentage of long chain UFA and lower percentage of saturated medium chain fatty acids, whereas A1/A2 individuals were intermediate for these values (p. 10). A2 derived milk has 3% more C18:1 than A1-derived milk, as a percentage of the total C18:1; the effect as a proportion of total milk fat was about half a percent more C18:1. The β-casein genotype accounted for 15-20% of the variation in these specific fatty acid compositions between the animals. The specification never actually discloses the levels of fatty acids in the particular types of milk, only the differences in levels in the contrasted genotypes. There is neither explicit nor implicit teaching of determining "the proportion" of cows that have particular genotypes.

The claims are sufficiently broad so as to encompass practicing the methodology on any herd of cows, wherein the cows may have a variety of different β-casein genotypes that were neither observed in the examples nor analyzed for their fatty acid content. Each of these genotypes is representative of a different molecular structure, and, it is highly unpredictable what the effects of the changes relative to A1 and A2 β-casein genotypes might be on the fatty acid content of the milk.

The technology area of this invention is highly unpredictable. At the time the invention was made, there was no known method for predicting based on genotype the levels of saturated or unsaturated fatty acids in milk. Further, it was known at the time the invention was made that genetic associations (that is the association between a phenotype and a genotype) are highly unpredictable. The results in Table 1 support the assertion that homozygous A1 versus A2 cows only displayed differences in certain types of fatty acids, while most fatty acids tested were not

significantly different by genotype. There is no guidance in the specification as to which proportion of genotypes would lead to particular levels of fatty acids in milk.

In order to enable the claimed invention, extensive experimentation would have to be carried out in a highly unpredictable technology area. The experimentation would require the analysis of milk from herds of cattle having different β-casein genotypes in order to determine the fatty acid composition, and then to determine the effects of different proportions of genotypes on the outcome of milk production. There is no guarantee of success, as here very limited guidance is given as to differences in milk fatty acid content among different β-casein genotypes and for a variety of different kinds of fatty acids.

Thus, having carefully considered these factors, it is concluded that it would take undue experimentation to practice the claimed invention.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday or Tuesday, from 9:00 AM until 4:30 PM, and Wednesday mornings from 8:00 AM until noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached by calling (571) 272-0763.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is

(571)272-0507.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/
Primary Examiner
Art Unit 1634

October 28, 2009